

This outline is provided as an EXAMPLE of a white paper to be submitted by vendors interested in obtaining certification and accreditation of a Digital Imaging (DI) System, Teleradiology (TR), or Picture Archiving Communications System (PACS). This outline is not all inclusive of the requirement, vendors must review all relevant references, DOD and Air Force Instructions, manuals and directives to meet the intent of this example outline and white paper format. Information provided will NOT be released to non-government agencies. The sole purpose of the data submission is for the government to determine a vendors ability to meet C2 and network security requirements.

**Example**

## **PACS and/or TR Vendor Security White Paper**

**Example**

- 1. Introduction**
- 2. System Architecture**
  - 2.1. PACS or TR Operational Concept**
  - 2.2. PACS or TR Modules**
    - 2.2.1. External Systems Interfaces**
      - 2.2.1.1. Composite Health Care System**
      - 2.2.1.2. Modalities**
      - 2.2.1.3. PACS Sites**
      - 2.2.1.4. MDIS Sites**
      - 2.2.1.5. TR Sites**
    - 2.2.2. Internal PACS or TR Modules**
      - 2.2.2.1. Workflow Servers**
      - 2.2.2.2. Quality Control Work Station**
      - 2.2.2.3. Web Server**
      - 2.2.2.4. Workstation Clients**
      - 2.2.2.5. Web Client Stations**
      - 2.2.2.6. RIS Gateway**
      - 2.2.2.7. RIS Server**
      - 2.2.2.8. RIS Workstation**
      - 2.2.2.9. RIS Reports Distribution Server**
      - 2.2.2.10. What ever is applicable???**
- 3. PACS or TR Block Diagram and Table of Information**
  - 3.1. PACS or TR Block Diagram**
  - 3.2. Table of Information**
- 4. Network Security**
- 5. Trusted Computing Base**
  - 5.1. Policy**
    - 5.1.1. Discretionary Access Control**
    - 5.1.2. Object Re-use**
  - 5.2. Accountability**
    - 5.2.1. Identification and Authentication**
    - 5.2.2. Audit**
  - 5.3. Assurance**
    - 5.3.1. Operational Assurance**
      - 5.3.1.1. System Architecture**
      - 5.3.1.2. System Integrity**
    - 5.3.2. Life Cycle Assurance and Security Testing**
  - 5.4. Documentation**
    - 5.4.1. Security Features User's Guide**
    - 5.4.2. Trusted Facility Manual**
    - 5.4.3. Test Documentation**
    - 5.4.4. Design Documentation**
- 6. List of References**

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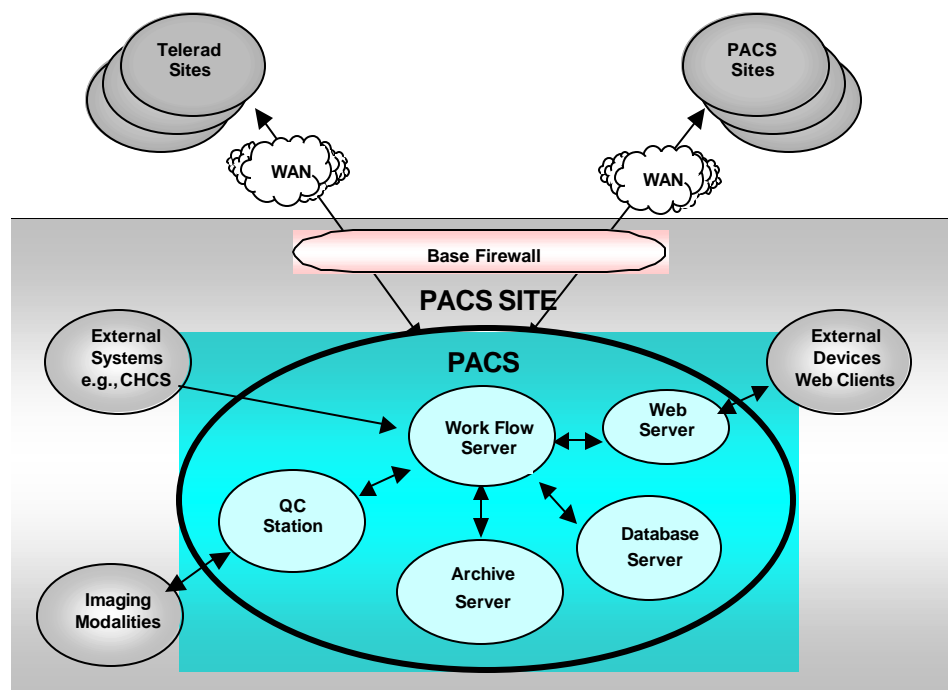
## Forward

The scope of this plan is for a PACS or TR TCB inside any Medical Treatment Facility (MTF) for which a delivery order would be awarded. It also includes security measures for any communications connections to external networks including the Defense Information Systems Network (DISN), the internet (Web Clients), connections to other MTFs (which may be PACS/TR sites), dial-up connections to remote user locations. Based on the approaches described in the paragraphs below, security policies and procedures specific to each site will be provided prior to Site Acceptance Testing.

### 1. Introduction

Digital Imaging (DI) initiative is the term used to describe the Air Force Medical Service systems for acquiring, managing, interpreting, reviewing, and storing diagnostic images and related patient information. This document describes the security architecture of the Picture Archiving and Communications System (PACS) and/or the Teleradiology (TR) system implementation. PACS and TR are terms used for the remainder of this document to describe the generic turnkey or Commercial-Off-the-Shelf (COTS) solutions to be delivered to the Government under the DIN-PACS II contract.

PACS comprises a trusted computing base (TCB). The figure below illustrates a high-level view of the PACS subsystems (or TR subsystems) and their relationships to external systems.



A TCB is defined as ...

## **2. System Architecture**

### **2.1. PACS or TR Operational Concept**

The following paragraphs describe a typical radiology workflow in terms of information flow within PACS/TR...

The patient arrives and demographics, exam information, and scheduling are entered into CHCS... a scenario for PACS or TR follows.

### **2.2. PACS or TR Modules**

#### **2.2.1. External Systems Interfaces**

External systems are typically those that will remain in place and be connected to the PACS/TR system being installed. This includes Government Furnished Equipment (GFE), such as printers, modalities, desktop PC's and Network components.

##### **2.2.1.1. Composite Health Care System (CHCS)**

PACS or TR interface to CHCS will be unidirectional. PACS or TR accepts all CHCS data elements required to support the following functions:

##### **2.2.1.2. Modalities**

Modalities are the image acquisition devices within a given MTF. Modalities include:

PACS or TR communications with the modalities is governed by the Digital Imaging and Communications in Medicine (DICOM) version 3.0, (NEMA PS 3.1-9, 1993) Service Classes as explained below:

- Remote Verification.
- Modality Worklist.
- Storage Commitment.
- Query/Retrieve.
- Remote Storage

##### **2.2.1.3. PACS Sites**

The system interface between PACS or TR and PACS sites will be implemented via DICOM, TCP/IP, HL7, etc... Explain how you would do this and how you would meet security requirements in doing so.

##### **2.2.1.4. MDIS Sites**

The system interface between PACS or TR and MDIS sites will be implemented via DICOM, TCP/IP, HL7, etc... Explain how you would do this and how you would meet security requirements in doing so.

##### **2.2.1.5. TR Sites**

The system interface between PACS or TR and TR sites will be implemented via DICOM, TCP/IP, HL7, etc... Explain how you would do this and how you would meet security requirements in doing so.

#### **2.2.2. Internal PACS or TR Modules**

In the paragraphs below, describe the individual modules in terms of their functionality. (List and describe modules that are applicable to your PACS or TR system.) Include in the discussion where applicable to each module the following topics: Passwords, Logins, Remote Access, Filesystem Access, Applications, Logging and Auditing, Access Control, Network Management, User Management, Map Event Tables, Examples of Error Level Logging, Examples of Debug Level Logging, Remote Access Protection and File Protection. Include further discussion that would enable the government to gain a better understanding of how your system works and the security features you employ.

#### 2.2.2.1. Workflow Servers

Include platform, operating system, configuration and workflow.

#### 2.2.2.2. Quality Control Work Station

Include platform, operating system, configuration and workflow.

#### 2.2.2.3. Web Server

Include platform, operating system, configuration and workflow.

#### 2.2.2.4. Workstation Clients

Include platform, operating system, configuration and workflow.

#### 2.2.2.5. Web Client Stations

Include platform, operating system, configuration and workflow.

#### 2.2.2.6. RIS Gateway

Include platform, operating system, configuration and workflow.

#### 2.2.2.7. RIS Server

Include platform, operating system, configuration and workflow.

#### 2.2.2.8. RIS Workstation

Include platform, operating system, configuration and workflow.

#### 2.2.2.9. RIS Reports Distribution Server

Include platform, operating system, configuration and workflow.

#### 2.2.2.10. What ever is applicable ???

Include platform, operating system, configuration and workflow.

### 3. PACS or TR Block Diagram and Table of Information

#### 3.1. PACS or TR Block Diagram

Provide a block diagram of your COTS PACS or TR product...

#### 3.2. Table of Information for ...Vendor Name... PACS or TR System

Item Name/COTS Name Hardware Description	Software Name/Release Number Version Number/Service Pack	Software Functional Description
Item Name: dBase Server HW:	Solaris, 8.0 ?	Operating System
		Database
		Login
		Calibration Application
		Display Support
		Library
		Cache Support
		client extensions
		dBase
		dB server extensions
		Service Tools
		WEB SERVICE
		Application Base Package
		Proxy Web Server
		Support package
		Dialup PPP
		Etc....

Item Name: Archive Server HW:	Solaris, 8.0 ?	Operating System
		Login
		Network Gateway
		MOD Jukebox archive
		Cache Support
		Client extensions
		dBase
		Service Tools
		Proxy Web Server
		Application Base Package
		Dialup PPP
		Support package
		Etc....
Item Name: Network Gateway HW:	Solaris, 8.0 ?	Operating System
		LOGINS
		Network Gateway
		MOD Jukebox archive
		Cache Support
		Client extensions
		DBase
		Service Tools
		Proxy Web Server
		Application Base Package
		Dialup PPP
		Support package
		Etc....
Item Name: QC Station HW: Intel Pentium IV, 1000 MHz	Microsoft NT Workstation 4.0, Service Pack xx	Operating System
	QC Station, version x.x.x	QC Station Software
	SCSI	CD-Writing Software
Item name: Web Server HW: Intel Pentium IV, 1500 MHz	Microsoft NT Server 4.0, Service Pack x	Operating System
	Microsoft SQL Server 7.0, Service Pack x	Database
	?	DICOM
	?	Java Runtime Environment
	128 bit	http Server
	Web 101	Application and Database Tables
Item Name: PACS Workstation HW: Intel Pentium IV, 1500 MHz	Microsoft NT Workstation 4.0, Service Pack x	Operating System
		PACS Workstation Application
	Client Applications	RIS Software
Item Name: Web Client Workstation HW: Government Furnished Equipment	Windows 2000, NT....	Operating System
	Netscape Navigator or Microsoft Internet Explorer (latest versions)	Web Browser
Item Name: RIS Gateway HW:	Microsoft NT Server 4.0, Service Pack x	Operating System
	Broker, v x , Service Pack x	HL7/DICOM gateway
	Microsoft SQL Server, v , Service Pack x	Database for RIS Gateway
	Report Interface, v xx	Web Server for retrieving reports
	Microsoft IIS	Microsoft Web Server
		Remote Software Maintenance
Item Name: RIS Server HW:	Open VMS 7.1	Operating System
	Server applications	Radiology Information System Application
	RDBMS v.	RDBMS
Item Name: RIS Workstation HW: Intel Pentium/IV PC	Microsoft NT 4.0, Service Pack xx	Operating System
	Client Applications	RIS Application
Item Name: RIS ?? Server HW: Intel Pentium/IV PC	Microsoft NT 4.0, Service Pack xx	Operating System
	Server Application	RIS ?? Server Application
Item Name: RIS ?? Server HW: Intel Pentium/IV PC	Microsoft NT 4.0, Service Pack xx	Operating System
	Server Application	RIS ?? Server Application

#### **4. Network Security**

This section addresses security considerations for both GFE, as well as vendor provided networks or network components. Specific MTF policies for firewall design, configuration, and implementation must be addressed in the network security architecture. This policy is needed to respond quickly and effectively to real or suspected breach or compromise of security system or policy. A thorough response policy will include analysis and policy development for the following:

- Intrusion and attack detection, identification and classification
- Attack containment, escalation procedures
- Assessing the full extent of attack and losses
- Assess the effectiveness of security strategies and policies
- Document the entire incident, providing recommendations for security architecture and policy improvement to prevent similar, future attacks
- Recovering from the attack.

#### **5. Trusted Computing Base**

It is a requirement that PACS or TR systems support C2 security, making users individually accountable through login procedures, auditing of security-relevant events, and resource isolation. In the following paragraphs describe the PACS or TR system attributes to meet or exceed minimal requirements for systems assigned a class (C2) rating.

This section of the document should be structured to follow the Orange Book requirements for a C2 level of trust. Each paragraph heading should correspond directly to a C2 requirement. Where applicable, the text body within each section may begin with the corresponding excerpt from the Orange Book. This is recommended for clarity, as well as, a road map for determination purposes.

##### **5.1. Policy**

The system security policy is a set of rules, and practices that regulate how the system manages, protects, and distributes sensitive information. Specifically, how are security events and policy violations (e.g., spoofing, denial of service attacks, unauthorized attempts to downgrade secure info, etc.) discovered. Explain how policies are enforced with regard to your PACS or TR system? Include the following subject areas in your discussion:

- Electronic Data Processing Security
- Communications Security
- Encryption of Sensitive Information and Data Circuits
- Personnel Security
- Physical Security

##### **5.1.1. Discretionary Access Control**

###### **Orange Book Requirement:**

“The TCB shall define and control access between named users and named objects (e.g., files and programs) in the ADP system. The enforcement mechanism (e.g., self/group/public controls, access control lists) shall allow users to specify and control sharing of those objects by named individuals, or defined groups of individuals, or by both, and shall provide controls to limit propagation of access rights. The discretionary access control mechanism shall, either by explicit user action or by default, provide that objects are protected from unauthorized access. These access controls shall be capable of including or excluding access to the granularity of a single user. Access permission to an object by users not already possessing access permission shall only be assigned by authorized users.”

##### **5.1.2. Object Re-use**

###### **Orange Book Requirement:**

“All authorizations to the information contained within a storage object shall be revoked prior to initial assignment, allocation or reallocation to a subject from the TCB's pool of unused storage objects. No information, including encrypted representations of information, produced by a prior subject's actions is to be available to any subject that obtains access to an object that has been released back to the system.”



## **5.2. Accountability**

### **5.2.1. Identification and Authentication**

#### **Orange Book Requirement:**

“The TCB shall require users to identify themselves to it before beginning to perform any other actions that the TCB is expected to mediate. Furthermore, the TCB shall use a protected mechanism (e.g., passwords) to authenticate the user's identity. The TCB shall protect authentication data so that it cannot be accessed by any unauthorized user. The TCB shall be able to enforce individual accountability by providing the capability to uniquely identify each individual ADP system user. The TCB shall also provide the capability of associating this identity with all auditable actions taken by that individual.”

### **5.2.2. Audit**

#### **Orange Book Requirement:**

“The TCB shall be able to create, maintain, and protect from modification or unauthorized access or destruction an audit trail of accesses to the objects it protects. The audit data shall be protected by the TCB so that read access to it is limited to those who are authorized for audit data. The TCB shall be able to record the following types of events: use of identification and authentication mechanisms, introduction or objects into a user's address space (e.g., file open, program initiation), deletion of objects, and actions taken by computer operators and system administrators and/or system security officers, and other security relevant events. For each recorded event, the audit record shall identify: date and time of the event, user, type of event, and success or failure of the event. For identification/authentication events the origin of request (e.g., terminal ID) shall be included in the audit record. For events that introduce an object into a user's address space and for object deletion events the audit record shall include the name of the object. The ADP system administrator shall be able to selectively audit the actions of any one or more users based on individual identity.”

## **5.3. Assurance**

### **5.3.1. Operational Assurance**

#### **5.3.1.1. System Architecture**

##### **Orange Book Requirement:**

“The TCB shall maintain a domain for its own execution that protects it from external interference or tampering (e.g., by modification of its code or data structures). Resources controlled by the TCB may be a defined subset of the subjects and objects in the ADP system. The TCB shall isolate the resources to be protected so that they are subject to the access control and auditing requirements.”

#### **5.3.1.2. System Integrity**

##### **Orange Book Requirement:**

“Hardware and/or software features shall be provided that can be used to periodically validate the correct operation of the on-site hardware and firmware elements of the TCB.”

### **5.3.2. Life Cycle Assurance and Security Testing**

#### **Orange Book Requirement:**

“The security mechanisms of the ADP system shall be tested and found to work as claimed in the system documentation. Testing shall be done to assure that there are no obvious ways for an unauthorized user to bypass or otherwise defeat the security protection mechanisms of the TCB. Testing shall also include a search for obvious flaws that would allow violation of resource isolation, or that would permit unauthorized access to the audit or authentication data.”

## **5.4. Documentation**

### **5.4.1. Security Features User's Guide**

#### **Orange Book Requirement:**

“A single summary, chapter, or manual in user documentation shall describe the protection mechanisms provided by the TCB, guidelines on their use, and how they interact with one another.”

### **5.4.2. Trusted Facility Manual**

#### **Orange Book Requirement:**

“A manual addressed to the ADP system administrator shall present cautions about functions and privileges that should be controlled when running a secure facility. The procedures for examining and maintaining the audit files as well as the detailed audit record structure for each type of audit event shall be given.”

### **5.4.3. Test Documentation**

#### **Orange Book Requirement:**

“The system developer shall provide to the evaluators a document that describes the test plan, test procedures that show how the security mechanisms were tested, and results of the security mechanisms' functional testing.”

### **5.4.4. Design Documentation**

#### **Orange Book Requirement:**

“Documentation shall be available that provides a description of the manufacturer's philosophy of protection and an explanation of how this philosophy is translated into the TCB. If the TCB is composed of distinct modules, the interfaces between these modules shall be described.”

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